UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ASTELLAS INSTITUTE FOR REGENERATIVE MEDICINE,

Plaintiff,

v.

IMSTEM BIOTECHNOLOGY, INC., XIAOFANG WANG, and REN-HE XU,

Defendants.

C.A. NO. 1:17-cv-12239-ADB

ASTELLAS' RESPONSE TO DEFENDANTS' PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

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Abbreviation	Term
’956 patent	U.S. Patent No. 8,961,956
’321 patent	U.S. Patent No. 8,962,321
’551 patent	U.S. Patent No. 9,745,551
ACT, ACTC	Advanced Cell Technology, Inc. (predecessor-in-interest to Astellas)
Astellas	Astellas Institute for Regenerative Medicine
Astellas Br.	Astellas’ Findings of Fact and Conclusions of Law, Dkt. 243
BIO	(2’Z,3’E)-6-Bromoindirubin-3’oxime, a GSK3 inhibitor
BM-MSC	Bone Marrow Mesenchymal Stem Cell
Def. Br.	Defendants’ Post-Trial Proposed Findings of Fact and Conclusions of Law, Dkt. 244
EAE	Experimental Autoimmune Encephalitis or Experimental Allergic Encephalomyelitis, an animal model of Multiple Sclerosis
EBs	Embryoid Bodies
ESCs	Embryonic Stem Cells
GSK3	Glycogen Synthase Kinase 3
GSK3i	Glycogen Synthase Kinase 3 Inhibitor
HB	Hemangioblast
HB-MSC	Hemangioblast-derived Mesenchymal Stem Cell
hESCs	Human Embryonic Stem Cells
IL-6	Interleukin 6 (a cytokine secreted by MSCs)
ImStem	ImStem Biotechnology, Inc.
IND	Investigational New Drug Application
MA09	A human embryonic stem cell line developed at ACT
MA09-MSC	An HB-MSC generated starting with MA09 human embryonic stem cells
MS	Multiple Sclerosis
MSCs	Mesenchymal Stem Cells
MTA	Material Transfer Agreement
Patent Office	U.S. Patent & Trademark Office
PCT	Patent Cooperation Treaty (a type of international patent application)
SCRMI	Stem Cell & Regenerative Medicine International, Inc. (predecessor-in-interest to Astellas)
T-MSC	Trophoblast-derived Mesenchymal Stem Cell
UConn	University of Connecticut

All emphasis added unless otherwise noted.

I. INTRODUCTION

In their post-trial brief, Defendants pick up right where they left off, elevating unsupported and fanciful testimony by interested witnesses above the actual, contemporaneous, written record. They even turn it up a notch, making never-before-raised arguments like "assignor estoppel" where there was ***never an assignment*** and "judicial estoppel" where there was ***never a judicial decision***, and relying on a half dozen exhibits that were ***never admitted into evidence***. Defendants are throwing everything at the wall hoping something sticks. Nothing does.

Astellas' case, in contrast, was based on the written record (including scores of scientific articles), supported by testimony of preeminent and well-informed experts who showed their work, and consistent with controlling law. The Court should find for Astellas on all issues.

II. DEFENDANTS' CASE ONLY WORKS BY IGNORING THE FACTS, CONTEMPORANEOUS DOCUMENTS, AND THE LAW

A. Defendants' Claims Of Scientific Complexity Ignore The Prior Art

1. Defendants argue they "were the first to fully conceive of the idea" of using Astellas' HB-MSCs to treat MS (Def. Br. ¶¶ 195, 26, *but see id.* ¶ 192 (alleging that "it was Drs. Wang and Xu (***with Dr. Lu***) who conceived of the idea")) and imply that, because the science is complex, only they could have conceived the alleged ideas due to their medical training (Def. Br. ¶¶ 59, 86-88, 211-13, 221-25). This fails for many reasons. First, if "medical training" were the test, Dr. Lanza, who is an M.D. with decades of experience in immunology and autoimmune diseases (Tr. 1-83:12-85:3; TX-IC), is the clear winner.[1] Regardless, the point is uninformative, as "educational and employment backgrounds" are "only weak circumstantial evidence with only a very attenuated relationship to [an alleged co-inventor's] potential contributions to the invention." *GemStar-TV Guide Int'l v. Int'l Trade Comm'n*, 383 F.3d 1352, 1382 (Fed. Cir. 2004).

[1] Dr. Lanza, unlike Defendants, has contemporaneous documents corroborating his idea to use HB-MSCs as therapies for numerous diseases, including MS. *See* Astellas Br. ¶¶ 1-5, 15.

2. Second, many prior art references showed Defendants' alleged ideas would work—no "superior insight" needed. Multiple papers and Defendants' own contemporaneous documents taught that MSCs could treat MS and worked in EAE. Astellas Br. ¶¶ 10-14, 64-68. Many papers taught IL-6 was an immunomodulating agent whose secretion by MSCs was commonly measured, and others taught the link between IL-6 levels and EAE and MS. *Id.* ¶¶ 17-18, 73-77. Defendants admitted in their sworn grant application that the literature showed IL-6 had already become "*a promising therapeutic target*." *Id.* ¶ 18. The same goes for mitotic inactivation. The literature taught it would work because a main way MSCs work is by secreting cytokines, which happens notwithstanding mitotic inactivation. *Id.* ¶¶ 21-23, 78-79. Dr. Bunnell opined[2] that regulatory agencies would require ESC-derived therapies to be mitotically inactivated for safety, and a skilled artisan would know how to titrate the radiation dose to inactivate the cells while maintaining their effect. *Id.* ¶ 22. Similarly, Dr. Xu admitted that comparing MSC types was "very common" and what scientists would naturally do. *Id.* ¶¶ 24, 80. Likewise for the '551 patent, serum- and feeder-free hESC culturing was known and routine before the collaboration. *Id.* ¶¶ 34-38, 82. Dr. Wang merely followed the teaching of Dr. Brivanlou's 2004, 2006, and 2009 publications—even acknowledging Dr. Brivanlou's 2004 paper in his draft presentation—arriving at his solution within 10 days and just two experiments. *Id.* ¶¶ 34-38, 83-87. Simply put, the prior art taught these ideas and that they would likely work. At best, Drs. Wang and Xu merely conveyed what the art already taught. That is not inventive. *Burroughs Wellcome Co. v. Barr Labs., Inc.*,, 40 F.3d 1223, 1227-28 (Fed. Cir. 1994); *Gen. Elec. Co. v. Wilkins*, 750 F.3d 1324, 1331-32 (Fed. Cir. 2014); *Eli Lilly & Co. v. Aradigm Corp.*, 376 F.3d 1352, 1362 (Fed. Cir. 2004).

[2] While criticizing his opinions on GSK3 inhibitors (Def. Br. ¶ 51), Defendants extol Dr. Brivanlou as "a stem-cell scientist for decades" to argue his statement on mitotic inactivation of MSCs deserves weight (*id.* ¶¶ 60-61, 181 n.33). They ignore that he was not opining on mitotic inactivation and had not reviewed the relevant literature. Tr. 4-22:9-23:4. In essence, Defendants argue Dr. Brivanlou should be treated as an expert on a subject on which he was uninformed and beyond his expertise and disregarded on a subject in which he is the world's leading expert.

B. Confirmatory Testing Not Required For Conception, Even If Science Is Complex

3. Even assuming the science is complex and Defendants' tests confirmed what the art taught, they would not be inventors. "An inventor need not know that his invention will work for conception to be complete. He need only show that he had the complete mental picture and could describe it with particularity; the discovery that the invention actually works is part of its reduction to practice." *Univ. of Pittsburgh of the Commonwealth Sys. of Higher Educ. v. Hedrick*, 573 F.3d 1290, 1298 (Fed. Cir. 2009). In *University of Pittsburgh*, the Federal Circuit affirmed a district court finding that two scientists, "Katz and Llull conceived of each claim of the invention through contemporaneous corroboration before the arrival of the [putative inventor] Hedrick." *Id.* As here, the named inventors invented a method to make MSCs (from fat) and, based on knowledge in the literature, recognized their MSCs were similar to BM-MSCs and had "properties known at the time to scientists in the field." *Id.* at 1294. Later, Hedrick joined Katz and Llull's lab and worked with them for a year. Hedrick then left their lab and, working elsewhere, "determined that the adipose-derived cells were distinct from the prior art [BM-MSCs]." *Id.* at 1294. The court expressly rejected Hedrick's argument that "Katz and Lull's work remained 'highly speculative'" and that they "were required to 'know' that the invention contained every limitation of each claim at the time of conception." *Id.* at 1299. Explaining that "[p]roof that the invention works to a scientific certainty is reduction to practice," the court held that, given Katz and Llull's conception, "it is immaterial that their knowledge was not scientifically certain and that [Hedrick] helped them gain such scientific certainty." *Id.* The Federal Circuit also expressly rejected Hedrick's argument that the district court improperly "fill[ed] in holes in Katz and Llull's conception with knowledge that a skilled artisan would have had at the time." *Id.* The Court explained "[e]vidence need not always expressly show possession of the invention to corroborate conception, and a court may properly weigh evidence that a claimed attribute is merely an obvious property of a greater

discovery at issue." *Id*. (citing *Burroughs Wellcome*, 40 F.3d at 1231).

4. That is precisely the case here. Drs. Lanza and Kimbrel invented a new method of making MSCs and had their cells in-hand. Astellas' Br. ¶¶ 1-5. They knew from the start that MSCs could treat many immune-related diseases, including MS. *Id.* While Drs. Wang and Xu's (and others') confirmatory data was important to the overall drug development process, it was not an inventive contribution under the law. The Court needn't adopt the false dichotomy that Drs. Wang and Xu are either inventors or, pejoratively, "technicians." *See* Def. Br. ¶ 38. What matters under the law is that each of their alleged contributions to both the Astellas patents and the '551 patent were properties that were known to skilled scientists at the time and thus cannot be a basis for inventorship.

C. Defendants Cannot Prove Inventorship Using Only Putative Inventor Testimony

5. While Defendants suggest providing corroboration may be "laughable" (*see* Def. Br. ¶ 27 n.10), it is ***required*** by Federal Circuit law. *Gen. Elec.*, 750 F.3d at 1330. And Defendants cite ***nothing*** but Drs. Wang and Xu's testimony for: 1) the discussion with Dr. Lu[3] where Drs. Wang and Xu allege they proposed using Astellas' HB-MSCs to treat MS; 2) the allegedly "first concrete mention of" MS; 3) the allegation that prior art Defendants described in their patent and internal documents as showing efficacy of MSCs in EAE and MS in fact only showed safety; 4) that they had access to other MSCs; or 5) the contention that they "designed a testing protocol" for and directed Dr. Wang's former lab at Yale, which had taught him the EAE model, how to run the EAE model with Astellas' HB-MSCs. *Id*. ¶¶ 32-33 & n.12, 39, 41 n.13.

[3] Defendants imply they did not cite Dr. Lu's testimony and relied only on Drs. Wang and Xu because "[n]either party produced Dr. Lu." Def. Br. ¶ 32 n.11. This is demonstrably false. Defendants deposed Dr. Lu and ***planned to play two hours of his deposition*** at trial. Dkt. 220 at 20. Defendants ultimately chose not to enter his testimony, but that was ***their*** choice, presumably because his testimony did not support their claim.

6. While Defendants cite follow-up emails to corroborate ***later*** meetings (*id.* ¶¶ 35-37), none record the alleged communication at the first meeting with Dr. Lu and none corroborate Defendants' alleged conception. *Eli Lilly*, 376 F.3d at 1363 (email "summariz[ing] a 'follow-up' on the July meeting, not the July meeting itself" does not corroborate testimony as to the July meeting). Emails Defendants cited to support that they "started sharing their results (and ideas) with Kimbrel and Lanza" ***were not admitted into evidence*** and show no such thing. Def. Br. ¶ 41 (citing TX-NB, TX-DS, & TX-EW).

7. Defendants also fail to corroborate their other alleged contributions. Defendants rely solely on Dr. Wang's testimony (which contradicts what he wrote in the book chapter) for the proposition that no one knew the effects of mitotic inactivation on cells generally and MSCs in particular. Def. Br. ¶¶ 56-59, 181-182. The same goes for Defendants' allegations that their idea to compare HB-MSCs with BM-MSCs "arose from [their] notion of using the cells to regulate the immune system,"[4] that the potency comparison allowed selection of therapeutically useful cells,[5] and that cells' potency can be dependent on a number of factors. *Id.* ¶¶ 66, 211. Defendants further fail to corroborate allegations that: 1) Dr. Wang "theorized that the low IL-6 might be relevant to" HB-MSCs' efficacy in MS; 2) his alleged theory regarding IL-6 was "counter to the conventional wisdom;" 3) "some scientists" had "shut down IL-6 secretion and found the MSCs to lose all therapeutic function;" 4) BM-MSCs may have had inadvertent IL-6 suppression; 5) low IL-6 cells are "better therapeutically;" 6) "IL-6 expression at a low level is not a fixed, inherent feature;" or 7) as HB-MSCs age "IL-6 levels increased and the cells became less therapeutically effective." *Id.*

[4] While Defendants also cite Dr. Bunnell's testimony (*id.* ¶ 66), Dr. Bunnell admitted he was told to ***assume*** Drs. Wang and Xu contributed this idea and did not undertake any analysis to assess who came up it (Tr. 7-57:19-25). He thus cannot corroborate Defendants' claim.

[5] Defendants cite four lines of Dr. Bunnell's testimony, but he only said comparison allowed HB-MSCs "and their biologic and therapeutic potential to be more understood." Tr. 7-73:25-74:5.

¶¶ 72-78, 177. Likewise Defendants did not corroborate allegations that: 1) "Dr. Xu's lab had access to and experience with multiple cell lines whereas ACT had just one;" 2) Drs. Wang and Xu "set about improving" Astellas' method "in order to advance the collaboration;" 3) Dr. Wang drew on just his experience to derive the GSK3 inhibitor concentration; 4) Dr. Wang used a GSK3 inhibitor "in an unexpected way" to promote cell differentiation; or 5) that using the GSK3 inhibitor yielded better and more EBs, HBs, and MSCs and improved their quality and quantity. *Id*. ¶¶ 42, 44-46, 49, 167-68. In short, Defendants based their case on unsupported say so.

D. Defendants' Experts Did Not Consider Relevant Evidence

8. Defendants engaged technical experts but chose to severely limit the scope of their opinions.[6] On the issues Defendants' experts did opine on, their opinions are fundamentally flawed. Dr. Bunnell did not search or consider the scientific literature on using MSCs for treating MS (Tr. 7-108:23-10:7), low IL-6 levels (Tr. 7-122:10-19), mitotic inactivation (Tr. 7-125:10-126:2), or comparison with BM-MSC (Tr. 7-132:6-16). He also did not consider Defendants' admissions in their book chapter concluding, based solely on prior art scientific literature, that MSCs could be mitotically inactivated because they work primarily via secreted factors or that it was known to compare new MSCs with BM-MSCs. Def. Br. ¶¶ 54, 59, 67; Tr. 7-132:17-133:3; TX-FD. Nor did he consider any lab notebooks or presentations on IL-6 data before trying to comment on Dr. Kimbrel's custom array work. Def. Br. ¶ 82; 7-118:7-25. Likewise, Dr. Perry saw "a few pages" of Dr. Wang's lab notebooks selected by counsel, but had no idea Dr. Wang selected his GSK3 inhibitor concentration in just two experiments within ten days and three notebook pages by following Dr. Brivanlou's prior work. Tr. 8-57:16-60:3. Why? He "wasn't invited" to watch

[6] Defendants continue to try to use Drs. Wang and Xu's uncorroborated testimony to substitute for expert opinion (*see, e.g.,* Def. Br. ¶¶ 7-10, 25, 53, 56-71, 74,76-77, 86)—a tactic the Court forbade. *See* 6/9/2020 Hr'g Tr. 14:10; Tr. 6-8:5-6 ("your witnesses are not going to testify as experts").

Dr. Wang's testimony. *Id.*

9. In stark contrast, Dr. Fortier surveyed the literature and parties' documents in forming her opinions. *See* Astellas Br. ¶¶ 7-8, 10, 12, 17, 21, 23-24, 52, 54. Defendants offer no real rebuttal, and instead disparage her as a veterinarian (Def. Br. ¶ 64), despite that she is a preeminent expert in both MSCs and animal modeling and despite Dr. Bunnell admitting "she's a very high-qualified scientist" (Tr. 7-98:17-21). Repeating conclusory phrases like Dr. Bunnell had a better "command of the relevant science" cannot change that he failed to study the relevant literature and record. Between an expert, Dr. Fortier, who engaged with the evidence and issues, and one, Dr. Bunnell, who did not, the former is more credible than the latter.

E. Defendants Mischaracterize Astellas' Patents and Prosecution History

10. Defendants mischaracterize Astellas' position to erect a straw man, that Astellas previously argued use of its HB-MSCs was separately inventive over the cells alone by filing the '956 patent and the '321 patent. *See* Def. Br. ¶¶ 188-190, 199. ***Not so***. Astellas' position has always been (and all the '321 and '956 claims require) the ***cells and the method of making them*** are inventive. The claims to therapeutic uses derive from the novel cells, not any alleged contribution by Defendants. *See, e.g.,* Dkt. 22 at 9-15; Astellas Br. ¶¶ 64-72. Defendants are also wrong in suggesting that the '321 patent is prior art to (or could invalidate) the '956 patent. *See In re Katz*, 687 F.2d 450, 454 (C.C.P.A. 1982) ("But certainly one's own invention, whatever the form of disclosure to the public, may not be prior art against oneself, absent a statutory bar"). Astellas has ***never*** argued or suggested, to either the Patent Office or to any court, that any of the features Defendants point to were themselves inventive; it has always been about the HB-derived cells.

11. Defendants incorrectly imply the inclusion of text from the January 2011 grant in Astellas' patents supports their inventorship claims. Def. Br. ¶ 91. First, this is irrelevant, as Defendants allege to have contributed only four things to Astellas' patents and they failed to

explain how any of the purported copied text relates to any of them. Defendants also mischaracterize the facts, completely omitting that Dr. Kimbrel sent Drs. Wang and Xu text (and data) for the January 2011 grant, including text "describing the differentiation procedure." Tr. 2-46:22-48:20; TX-22. Some of the text Defendants highlighted as copied from them is, in fact, text that ***Defendants copied nearly verbatim from Dr. Kimbrel*** (differences underlined):

TX-22 at IMSTEM-1632 December 2010 Kimbrel Text	**TX-CC-A at AIRM14757 January 2011 Grant App.**	**TX-35A at 7 Astellas' Provisional App.**
"Going through an intermediate hemangioblast stage prior to further differentiation enables a rapid expansion of multipotent cells, facilitates large scale production of mature cell populations further downstream, and does not require labor-intensive hand-picking."	"Going through an intermediate HB stage prior to further differentiation enables a rapid expansion of multipotent cells, facilitates large-scale production of mature populations further downstream, and does not require labor-intensive handpicking."	"[G]oing through an intermediate hemangioblast stage prior to further differentiation, permits a rapid expansion of multipotent cells, facilitates large scale production of mature cell populations further downstream, and does not require labor-intensive hand-picking."

Far from supporting Defendants' inventorship claims, this is just one more example of Defendants improperly (and misleadingly) trying to claim Astellas' work as their own.

12. Defendants' suggestion that a feature is inventive if recited in a dependent claim (Def. Br. ¶ 220) is contrary to law—a person "does not necessarily attain the status of co-inventor by providing the sole feature of a dependent claim." *Nartron Corp. v. Schukra U.S.A., Inc.*, 558 F.3d 1352, 1358 (Fed. Cir. 2009); *see* Astellas Br. ¶ 75. Indeed, Defendants admitted, in sworn interrogatory answers, the '551 dependent claims did not have ***any*** independently inventive features (excepting BIO). While they ultimately reneged on that admission as a litigation tactic, they were right the first time, both in acknowledging the black letter legal premise that dependent claims need not add inventive features and the fact that the features were not, indeed, inventive.

13. Defendants assert they should be inventors on Astellas' patents because their contributions are similar to those by inventor Dr. Kouris. Def. Br. ¶¶ 82 n.16, 95-98, 204-07. The

factual assertion fails. Astellas Br. ¶ 76. The comparison is so flimsy, Defendants offered no expert testimony, or testimony from Drs. Wang and Xu, in support. On complex technological issues like this, attorney argument is insufficient. *See Alexsam, Inc. v. IDT Corp.*, 715 F.3d 1336, 1347-48 (Fed. Cir. 2013) ("expert testimony regarding matters beyond the comprehension of laypersons is sometimes essential, particularly in case involving complex technology") (quotations omitted).

III. DEFENDANTS' UNFAIR TRADE PRACTICES DEFENSES[7] FAIL

1. Evidence Proves ImStem Was Founded Using Astellas' HB-MSC Technology

14. Defendants argue they did not rely on Astellas' HB-MSC technology to form ImStem, as if their contemporaneous documents do not exist and Dr. Wang never testified. Defendants expressly referenced HB-MSC, not T-MSC, in business plans predating ImStem's founding and to secure a $1.13 million grant for ImStem. *See* Astellas Br. ¶¶ 49, 51-52. Defendants admit they sent HB-MSC data in the March 2012 business plan to their major investor, Dr. Men (Def. Br. ¶ 126), and used HB-MSC data to show him they "have the expertise to do experiment related to MSC technology development"—expertise they would not have had but for working with Astellas' cells. Tr. 6-127:2-25. Defendants further inferred from Astellas' HB-MSC the "advantages of hESC-MSCs to adult tissue-derived MSCs." Def. Br. ¶ 125. Defendants continue to falsely claim they never disclosed Dr. Kimbrel's HB-MSC protocol to investors (Def. Br. ¶ 127), despite now admitting they sent Dr. Men HB-MSC data in an ImStem business plan (*id.* ¶ 126). Defendants are still wrong as to the protocol, as Dr. Wang disclosed it to Dr. Men. Tr. 6-188:19-189:6; *see* Astellas Br. ¶ 50. Thus, Defendants used Astellas' HB-MSC to secure investors and only evolved after doing so. Def. Br. ¶ 126; TX-18; TX-AH. Even after switching focus to T-MSC, Defendants continued to falsely present HB-MSC data as T-MSC data to seek regulatory approval,

[7] Defendants' short argument that unclean hands bars this claim (Def. Br. ¶¶ 234-37) also fails. Defendants' inventorship claims are meritless as Astellas explained. Also, unclean hands requires more outrageous conduct than a mistaken disclosure followed by an apology and remedying steps.

obtain grants, and show T-MSC "work all the same" as HB-MSC. *See* Astellas Br. ¶¶ 56-58.

2. Defendants' MTA Arguments Are Irrelevant And Mischaracterize The Facts

15. Defendants continue to mischaracterize the parties' exchanges regarding the MTA, accusing Astellas of "clawing back" a proposal (Def. Br. ¶ 102). In fact, all the email chain between Dr. Gallo and Dr. Vincent shows is Dr. Gallo sent redlines to Dr. Vincent, Dr. Vincent said those edits did not work, proposed some alternatives, and asked to discuss them, and Drs. Gallo and Vincent discussed a time for a call. TX-XV. Defendants provide no evidence—only attorney argument—for their contrary assertion. Notably, Defendants never deposed or offered at trial either of the negotiators—Dr. Gallo for UConn or Dr. Vincent for ACT—instead relying only on testimony from Drs. Wang and Xu—who both admitted they didn't know the details, having "handed it to" Dr. Gallo. Tr. 10-39:24-40:6, 6-119:10-16.

IV. DEFENDANTS' DESPERATION IS CLEAR FROM THEIR RELIANCE ON EXHIBITS NOT ENTERED INTO EVIDENCE

16. Even in the rare instances Defendants cite to documents, ***six were never entered into evidence***. Defendants quote an email, TX-OF, never entered into evidence, to allege Astellas knew ImStem existed by May 2013. *See* Def. Br. ¶¶ 128-130. They likewise cite TX-DS, TX-EW, TX-NB, and TX-SI, emails that allegedly support Defendants' claim that Drs. "Wang and Xu started sharing their results (and ideas)" with Astellas, but were never in evidence. *See* Def. Br. ¶ 41. Finally, Defendants rely on the file histories of Astellas' patents (TX-FG, TX-48; *see* Def. Br. ¶¶ 93, 130, 131), which were not entered into evidence. Of course the Court should ignore all of this non-evidence and the alleged "facts" they support.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document, which was filed with the Court through the CM/ECF system, will be sent electronically to all registered participants as identified on the Notice of Electronic Filing, and paper copies will be sent on December 11, 2020 to those identified as non-registered participants.

/s/ *David P. Frazier*
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